



## **ATTACHMENT 6a**

FEB - 3 1994

W. Dale Parker  
Claxton Bakery, Inc.  
P.O. Box 367  
Claxton, GA 30417

Dear Mr. Parker:

This is in response to your letter of May 31, 1993 to Dr. Scarbrough requesting a change in the serving size definition for fruit cake. You stated that your fruit cakes, which contain 72 percent fruit and nuts, are very dense and heavy and that the 1-fourth pound (4 ounce) serving size required by the new regulations would be unreasonable. You indicated that your traditional serving size has been 1 ounce and that you feel this is a generous portion for your product.

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) required that the Food and Drug Administration (FDA) establish regulations for serving sizes that would reflect the "amount customarily consumed." FDA reviewed consumption data, and, in the November 27, 1991 Federal Register (56 FR 60394), the agency proposed 125 g as the reference amount for heavy cakes (defined as cakes weighing 10 g or more per cubic inch). Comments received in response to the proposal convinced the agency that the density-based criterion should be changed. Therefore, in the January 6, 1993 Federal Register (58 FR 2229), FDA established 125 g as the reference amount for heavy weight cakes including fruit cakes (defined as cakes containing 35% or more of the finished weight as fruits, nuts, or vegetables). Thus, in accordance with §101.9(b)(2)(ii), the serving size for a 1-pound (453.6 g) fruit cake would be "1/4 cake (113 g)" which is consistent with your calculations.

In preparing the final serving size regulation, FDA responded to all comments received. The agency did not receive a specific request for a "very heavy weight cake" category. Now that final regulations are established, the process for creating a new subcategory involves formally petitioning the agency in accordance with the provisions in §101.12(h) which include providing a suggested reference amount, data demonstrating significant differences in consumption from the parent category, and documentation supporting differences in dietary usage and product characteristics.

Page 2 - Mr. W. Dale Parker

However, in the interim, 21 CFR 101.9(b)(10)(i) provides for a voluntary second column of nutrition information on a 1 ounce basis. For fruit cake products, the first column would provide nutrition information in terms of the serving size declared as the common household measure closest to the reference amount of 125 g, "1/4 cake (113 g)," and the second column would provide nutrition information on 1 ounce of fruitcake in accordance with the provisions for ounce declarations in 21 CFR 101.9(b)(2)(iii), "1 oz (28 g/1/16 cake)." Finally, the serving size declaration on your proposed label states "1/4 lb. (114 g) - 4 oz" which is incorrect and not permitted.

We hope this information is helpful in clarifying the serving size situation for fruit cakes. Please contact us if you have any additional questions or if we can be of any further assistance.

Sincerely yours,

Ellen Anderson, Ph.D.  
Research Chemist  
Division of Technical Evaluation  
Office of Food Labeling  
Center for Food Safety  
and Applied Nutrition

## **ATTACHMENT 6b**

FEB - 3 1994

Perkins Williams  
Benson's Inc.  
P.O. Box 429  
Bogart, GA 30622-0429

Dear Mr. Williams:

This is in response to your letter of August 17, 1993 to Dr. Scarbrough requesting a change in the serving size definition for fruit cake. You stated that a 4-ounce serving size is unreasonable since the average person will not consume 4 ounces of fruit cake at one time and that 1.5 ounces would be more reasonable.

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) required that the Food and Drug Administration (FDA) establish regulations for serving sizes that would reflect the "amount customarily consumed." FDA reviewed consumption data, and, in the November 27, 1991 Federal Register (56 FR 60394), the agency proposed 125 g as the reference amount for heavy cakes (defined as cakes weighing 10 g or more per cubic inch). Comments received in response to the proposal convinced the agency that the density-based criterion should be changed. Therefore, in the January 6, 1993 Federal Register (58 FR 2229), FDA established 125 g as the reference amount for heavy weight cakes including fruit cakes (defined as cakes containing 35% or more of the finished weight as fruits, nuts, or vegetables). Thus, in accordance with §101.9(b)(2)(ii), the serving size for a 1-pound (453.6 g) fruit cake would be "1/4 cake (113 g)."

In preparing the final serving size regulation, FDA responded to all comments received. The agency did not receive a specific request for a "very heavy weight cake" category. Now that final regulations are established, the process for creating a new subcategory involves formally petitioning the agency in accordance with the provisions in §101.12(h) which include providing a suggested reference amount, data demonstrating significant differences in consumption from the parent category, and documentation supporting differences in dietary usage and product characteristics.

However, in the interim, 21 CFR 101.9(b)(10)(i) provides for a voluntary second column of nutrition information on a 1 ounce basis. For fruit cake products, the first column would provide nutrition information in terms of the serving size declared as the common household measure closest to the

Page 2 - Mr. Perkins Williams

reference amount of 125 g, "1/4 cake (113 g)," and the second column would provide nutrition information on 1 ounce of fruitcake in accordance with the provisions for ounce declarations in 21 CFR 101.9(b)(2)(iii), "1 oz (28 g/1/16 cake)."

We hope this information is helpful in clarifying the serving size situation for fruit cakes. Please contact us if you have any additional questions or if we can be of any further assistance.

Sincerely yours,

Ellen Anderson, Ph.D.  
Research Chemist  
Division of Technical Evaluation  
Office of Food Labeling  
Center for Food Safety  
and Applied Nutrition

# **ATTACHMENT 6c**



FEB 18 1994

Mr. Ernest R. Stolzer  
Quality Bakers of America  
Cooperative, Inc.  
70 Riverdale Avenue  
Greenwich, CT. 06830

Dear Mr. Stolzer:

This is in response to your letter of August 25, 1993 to Dr. Scarbrough requesting a change in the serving size definition for fruit cake. You stated that a 4-ounce serving size is unreasonable since the average person will not consume 4 ounces of fruit cake at one time and that 1.5 ounces would be more reasonable.

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) required that the Food and Drug Administration (FDA) establish regulations for serving sizes that would reflect the "amount customarily consumed." FDA reviewed consumption data, and, in the November 27, 1991 Federal Register (56 FR 60394), the agency proposed 125 g as the reference amount for heavy cakes (defined as cakes weighing 10 g or more per cubic inch). Comments received in response to the proposal convinced the agency that the density-based criterion should be changed. Therefore, in the January 6, 1993 Federal Register (58 FR 2229), FDA established 125 g as the reference amount for heavy weight cakes including fruit cakes, but modified the definition of heavy weight cakes to be defined as cakes containing 35% or more of the finished weight as fruits, nuts, or vegetables. Thus, in accordance with §101.9(b)(2)(ii), the serving size for a 1-pound (453.6 g) fruit cake would be "1/4 cake (113 g)."

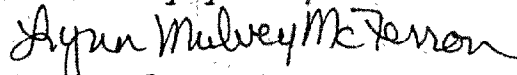
In preparing the final serving size regulation, FDA responded to all comments received. The agency did not receive a specific request for a "very heavy weight cake" category. Now that final regulations are established, the process for creating a new subcategory involves formally petitioning the agency in accordance with the provisions in §101.12(h) which include providing a suggested reference amount, data demonstrating significant differences in consumption from the parent category, and documentation supporting differences in dietary usage and product characteristics.

Page 2 -- Ernest Stolzer

However, in the interim, 21 CFR 101.9(b)(10)(i) provides for a voluntary second column of nutrition information on a 1 ounce basis. For fruit cake products, the first column would provide nutrition information in terms of the serving size declared as the common household measure closest to the reference amount of 125 g, "1/4 cake (113 g)," and the second column would provide nutrition information on 1 ounce of fruitcake in accordance with the provisions for ounce declarations in 21 CFR 101.9(b)(2)(iii), "1 oz (28 g/1/16 cake)."

We hope this information is helpful in clarifying the serving size situation for fruit cakes. Please contact us if you have any additional questions or if we can be of any further assistance.

Sincerely yours,



Lynn Mulvey McFerron  
Nutritionist  
Division of Technical Evaluation  
Office of Food Labeling  
Center for Food Safety and  
Applied Nutrition

# **ATTACHMENT 6d**

JUN 17 1994

Ms. Kay Jacob  
Armour, Swift & Eckrich  
3131 Woodcreek Drive  
Downers Grove, Illinois 60515

Dear Ms. Jacob:

This letter responds to your phone call of May 18, 1994 requesting information on serving size for fruitcakes.

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) required that the Food and Drug Administration (FDA) establish regulations for serving sizes that would reflect the "amount customarily consumed." FDA reviewed consumption data, and, in the November 27, 1991 Federal Register (56 FR 60394), the agency proposed 125 g as the reference amount for heavy cakes (defined as cakes weighing 10 g or more per cubic inch). Comments received in response to the proposal convinced the agency that the density-based criterion should be changed. Therefore, in the January 6, 1993 Federal Register (58 FR 2229), FDA established 125 g as the reference amount for heavy weight cakes, including fruit cakes, but modified the definition of heavy weight cakes, to include cakes containing 35% or more of the finished weight as fruits, nuts, or vegetables. Thus, in accordance with §101.9(b)(2)(ii), the serving size for a 1-pound (453.6 g) fruit cake would be "1/4 cake (113 g)."

In preparing the final serving size regulation, FDA responded to all comments received. The agency did not receive a specific request for a "very heavy weight cake" category. Now that final regulations are established, the process for creating a new subcategory involves formally petitioning the agency in accordance with the provisions in §101.12(h) which include providing a suggested reference amount, data demonstrating significant differences in consumption from the parent category, and documentation supporting differences in dietary usage and product characteristics.

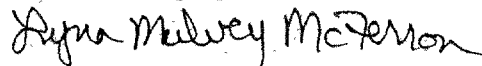
However, in the interim, 21 CFR 101.9(b)(10)(i) provides for a voluntary second column of nutrition information on a 1 ounce basis. For fruit cake products, the first column would provide nutrition information in terms of the serving size declared as the common household measure closest to thereference amount of 125 g, i.e. "1/4 cake (113 g)," and the second column would provide nutrition information on 1 ounce

Ms. Kay Jacob

of fruitcake in accordance with the provisions for ounce declarations in 21 CFR 101.9(b)(2)(iii), "1 oz (28 g/1/16 cake)."

We hope this information is helpful in answering your questions regarding the serving size for fruit cakes. Please contact us if we can be of further assistance.

Sincerely yours,



Lynn Mulvey McFerron  
Nutritionist  
Division of Technical Evaluation  
Office of Food Labeling  
Center for Food Safety and  
Applied Nutrition